Instructions for Use - EN

TRV Chair

Rev. No. 2. – 2016/09

Contents

1 Introduction

1.1 About this manual

This manual is valid for TRV Series III.2 and Series III.3. The equipment is manufactured by:

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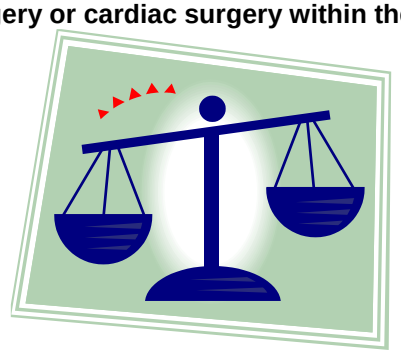
1.2 Intended use

The Vertigo Treatment and Rehabilitation (TRV) Chair is a consultation chair designed for diagnostic and therapeutic maneuvers for patients suffering from positional vertigo.

The Vertigo Treatment and Rehabilitation (TRV) Chair is intended to be used by an audiologist, hearing healthcare professional or trained technician. The instrument is intended for the diagnosis and treatment of patients presenting with imbalance, unsteadiness or dizziness symptoms suspected of originating from dislocated otoconia in one or more of the semicircular canals in the inner ear.

Contraindications
This device must not be used for patients weighing more than 150 kg. It must also not be used if the patient presents with unusual headache symptoms, uncontrolled high blood pressure or some associated neurological symptoms or any other atypical findings. It must not be used if the patient has undergone neurosurgery or cardiac surgery within the past month.



READ THE ENTIRE MANUAL BEFORE ATTEMPTING TO USE THE SYSTEM!
Use this device only as described in this manual.

1.3 Notes on safety

Our instruction manuals contain safety notes which follow the ANSI recommendations (American National Standards Institute) for safety notes.

	**WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	**CAUTION**, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	**NOTICE** is used to address practices not related to personal injury.

The TRV chair is a Class 1 medical device according to IEC 60601-1 for medical diagnostics and physiotherapy.

1.4 Safety instructions

To ensure correct use of the medical device, it is essential to read this documentation and all the instructions and labels carefully and thoroughly.

The system should not be used in areas of high humidity.
The system should not be exposed to explosive or flammable gases.

The system should only be used by persons who have been trained in its use and who are medically qualified in the field of vestibulometry.

In the event of damage to the system or any of its components, it must be repaired before further use.

Always switch the system off before cleaning.

The use, sale and distribution of the system may be regulated, so it is essential to ensure that the device is compliant with any local regulations before being put into use.

2 Unpacking and installation

2.1 Unpacking and inspection

When opening the transportation crate, first remove the top cover. Verify that all support beams are in place and that the chair has not been able to move during its transportation.

Inspect the painting, the metal surfaces, the integrity of the seat and the saddlery. Also check if there is any rust.

2.1 Meaning of symbols used

SYMBOL	DESCRIPTION
	Consult Operating Instruction
	CE mark
	Manufacturer
	Date of manufacture
	Serial number
	Fragile, handle with care
	Keep dry
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discharge this product, it must be sent to separate collection facilities for recovery and recycling.

3 System description & performance

The TRV consultation chair has a seat equipped with supports (four-point harness, headrest with headband and leg strap) and has two axes of rotation which are lockable in preset positions.

The horizontal axis is locked by means of an electromagnetic lock (footswitch operated) with the patient in one of the following positions:

1. Standard (vertical, head at top).
2. 30° above the horizontal plane for caloric tests.

3. 0° or 180° (supine decubitus, left or right decubitus or ventral decubitus.

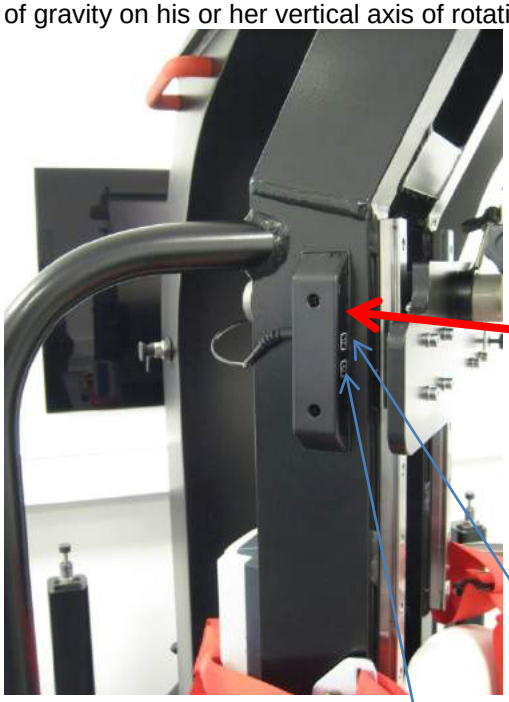



)

4. Immobilization -45° or +225° (45° below the horizontal plane, head to left or right) for “potentiated” Epley maneuver:

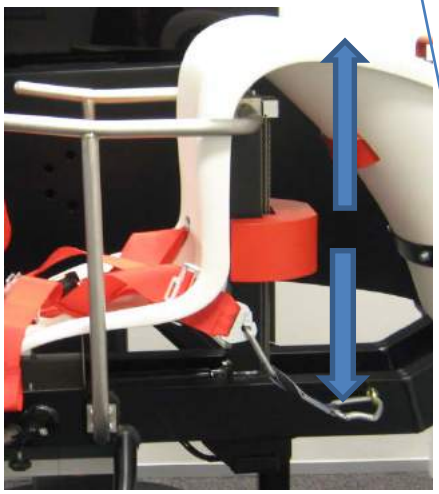
The vertical axis can be locked by means of a manually operated lock with the patient in the standard position (facing the operator) and then locked at every subsequent 45°:

A servo-controller under the patient's seat is used to move a counterweight to adjust the patient's center of gravity on his or her vertical axis of rotation:



Control panel with switches for movement of counterweight.

The counterweight must be in the center position for average weight patients (60-90kg)



On very light patients: Press the upper button to move the counterweight towards the patient's knees.

On very heavy patients: Press the lower button to move the counterweight away from the patient's knees.

This will ensure a well-balanced rotation during diagnostic procedures and during the barbecue maneuvers.
The height position of the headrest and the headband can be adjusted to the patient's height by means of a pneumatic lift. The operator pushes a release button and raises or lowers the headrest so that it is in line with the patient's head position:

Release button:
Press and hold to adjust the position of the headrest.

The chair enables the operator to rotate the patient in planes that are very close to the planes of each of the semicircular canals:

Rotations 45° from the sagittal plane will stimulate the anterior or posterior canals, and barbecue rotations along the vertical plane will stimulate the horizontal canals.

These maneuvers are possible in more than full-circle rotations (+360°).

Rotation must only be performed on one axis at a time.
Maneuvers on the horizontal axis can be arrested in two positions by means of a retractable stop:

- In the horizontal plane (for Dynamic Particle Repositioning Maneuvers (DPRM), also known as the TRV maneuver).

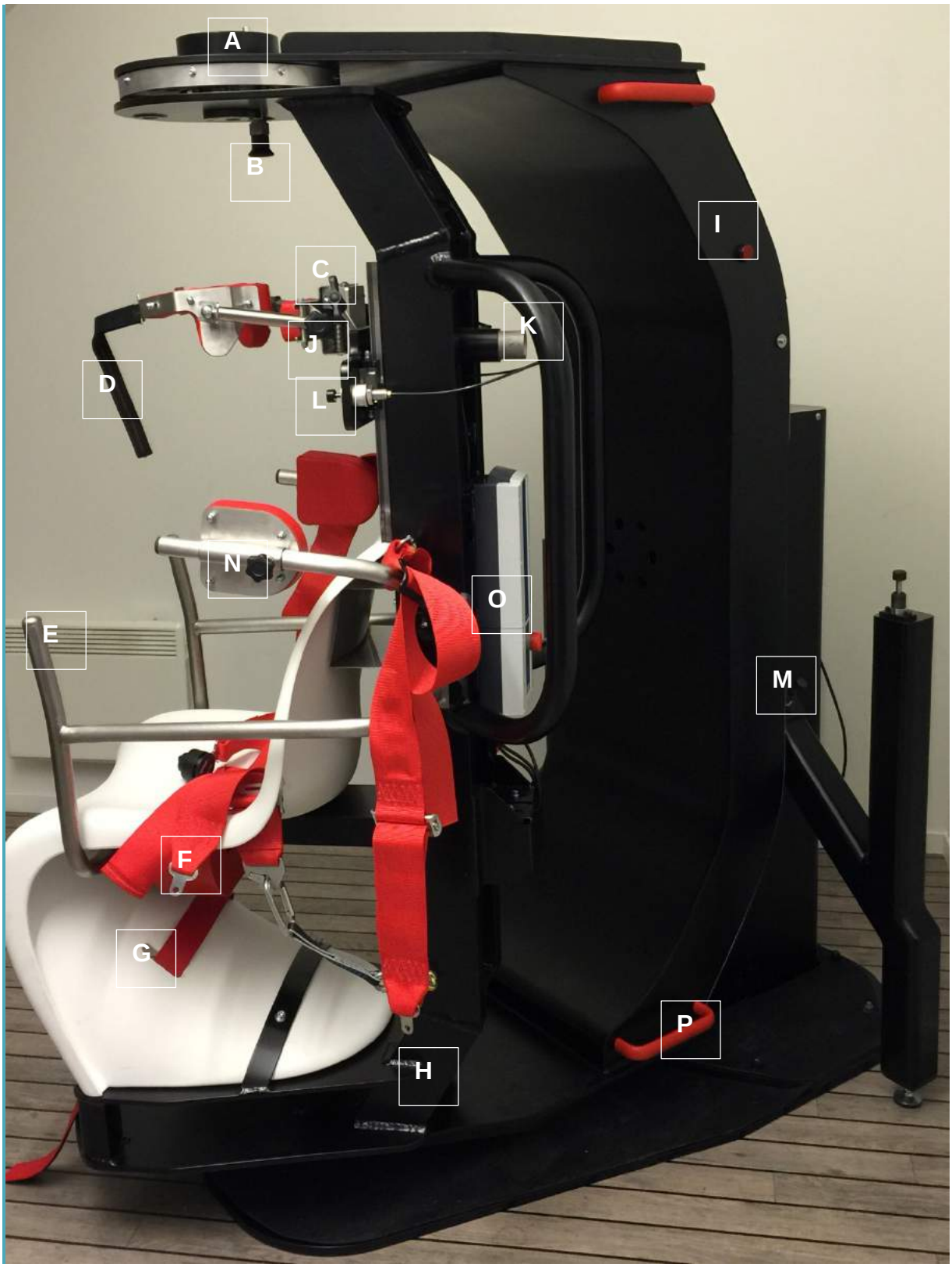
Stop position for horizontal canal DPRM.

Stop will engage with upper hydraulic shock absorbe.r during horizontal canal DPRM

- At 45º below the horizontal plane (for Sémont and Epley maneuvers) to increase therapeutic efficacy:

Stop position for Sémont and Epley maneuvers.

Stop will engage with lower hydraulic shock absorber during vertical canal DPRM.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Key to picture on page 9:

A Secondary Frame rotation axis

B Secondary Frame lock - lockable every 45°

C Headrest forward travel locking screw

D Headrest locking system

E Handle for patient

F Motorized movable counterweight

G Leg strap

H Secondary frame

I Red light on when electromagnetic locking system of the primary frame is unlocked

J Headrest left temporal support locking screw

K Secondary frame and carrying handle

L Headrest upward and downward travel locking button

M Primary frame shock absorber for Sémont maneuvers

N Shoulder support

O Power unit for counterweight servo-controller

P Primary frame and carrying handle

3.1 Spare part list

The spare parts below are available for the product:

CTRV Item #	Description
100	Shock absorber
103	Gas spring system for headrest
106	Release button for headrest lift system
114	Red handle
118	Manual locking system for retractable stop
119	Manual locking system for the secondary frame
120	Battery holder for counterweight electric lift system or electromagnetic locking system for the primary frame
121	Wall mounted charger for 24v battery
123	24v battery
124	Support for the control box
125	Wall support for battery charger
126	Switch panel for counterweight operation
127	Electromagnetic locking system for primary cradle
128	Nuchal saddlery and foam with support
129	Additional black covered foam block for the back of the patient
130	Leg strap
131	Frontal headstrap
132	Shoulder/arm saddlery and foam with support right or left
133	Temporal saddlery and foam with support right or left
134	Four-point harness
135	Foot switch for electromagnetic locking system
136	Red light signal for electromagnetic locking system status
140	Plastic seat insert
141	Rubber carpet for the foot plate
201	Primary axle
202	Upper secondary frame axle
203	Lower secondary frame axle
205	Complete block with bearing for secondary frame axle, upper and lower
305	Painted slip-rings cover for secondary frame (upper)
306	Painted cover for bearing of secondary frame (lower)
	Cable set with slip-rings

4 Using the chair

4.1 Precautions for use – basic safety rules

► Do not use for patients weighing more than 150 kg
► Do not use for patients taller than 195cm or shorter than 140cm► Before seating a patient, make sure that both axle locks are in their locked positions
► Never release both axle locks at the same time
► Never release the primary frame lock when there is no patient in the chair
► No one except the operator and the patient should stand closer than 2 meters from the chair

- No modification of this equipment is allowed without CTRV INNOVATION authorization

Potential side effects:

- Patients presenting with moderate headache may experience a worsened condition after the treatment
- Patients presenting with nausea may be at risk of vomiting during the diagnostic and therapeutic maneuvers. They must be requested to alert the operator as early as possible if they are about to vomit so the operator can terminate the procedure, put the patient in the upright position, remove the goggles and open the harness and leg strap. A container must be kept available to collect any vomit.

Connection to other medical devices

- The TRV chair is constructed for use with the IEE1394a FireWire™ Video Frenzel or VNG systems from Interacoustics A/S or Micromedical Technologies. Eye images are recorded by means of infra-red video cameras mounted on the goggles. A cable connection with two sets of slip-rings conducts the video signal from the cameras, through the 2 axles, to a computer. The eye images are analyzed and displayed on an external screen for optimal observation of nystagmus during the diagnostic and therapeutic procedures.

Precautions to be taken in the event of changes in the performance of the device:

- The manufacturer should be advised of any change in the performance of the device. The device should be taken out of use and not returned to use until the necessary corrective actions, as specified by the manufacturer, have been carried out.

4.2 Seating the patient

Once the patient is seated, if the chair is only to be used for a conventional consultation in which only the vertical axis is released, for example in order to examine one ear and then the other without the operator needing to move, no supporting device is necessary.

If the patient is due to be diagnosed and treated for positional vertigo, supporting devices are essential and should be placed as follows:

Adjust the headrest according to the height of the upper body by means of the release button.

Leave enough space above the eyebrows to allow the headstrap to be tightened without interfering with the VNG goggles.

4.2.1 Fitting the harness:

To fit the harness, start with the abdominal strap; this should be placed as low as possible, below the abdomen, at the root of the thighs, so as to immobilize the pelvis. Pull the strap as tight as possible.

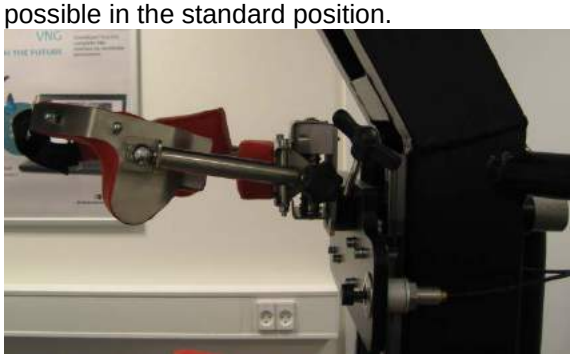
The central buckle should remain in the middle and the strap adjusted alternately to left and right so as to keep it in that position. Maximum tightness can be obtained by pressing the strap with the flat of the hand against the side of the pelvis, using the other hand to pull on the free end of the strap; do this on each side in turn.

Next, the two shoulder straps are fitted and tightened by pulling the free end of the strap downwards to ensure full patient support.

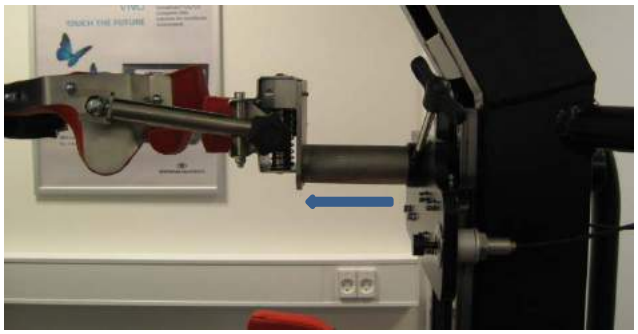
When each strap is fitted into the central buckle, there should be a clearly audible click. Pull on each strap to make sure it is locked in position. Then adjust the shoulder supports.

4.2.2 Placing the headrest:

Adjust the headrest so that the headstrap leaves a space of approximately 2 cm above the eyebrows for the VNG goggles. The VNG goggles should be fitted before adjusting the headstrap. The purpose of this strap is to hold the head steady so as to prevent any anteroposterior movements.
With kyphotic or scoliotic patients, the headrest should be moved forwards to the nape if support is not possible in the standard position.



Head support in standard position.



Head support in extended position.

The lower legs are supported by a strap which holds the ankles tightly against the chair:

Never release the horizontal axis unless the patient is held by all of the four supporting devices, which must be correctly adjusted

1. 4-point harness.
2. Shoulder supports.
3. Head support with properly tightened headstrap.
4. Leg strap .

To release the axle, press the foot switch. When the red lights on both sides of the primary frame are on, the magnetic locking system will be released by a slight pull or push of the primary frame.
The vertical axle is released by pulling the lock button downwards. It is automatically brought back to the locked position by a return spring.

To keep the vertical axle permanently unlocked for barbecue maneuvers etc., pull the button to its fully down position and give it a quarter-turn left or right to prevent it from returning to the locked position. On TRV Series III.2 chairs, use the lock at the front for the diagnostic and therapeutic maneuvers and the lock on the left side for the standard position and while the patient is being secured in the chair.

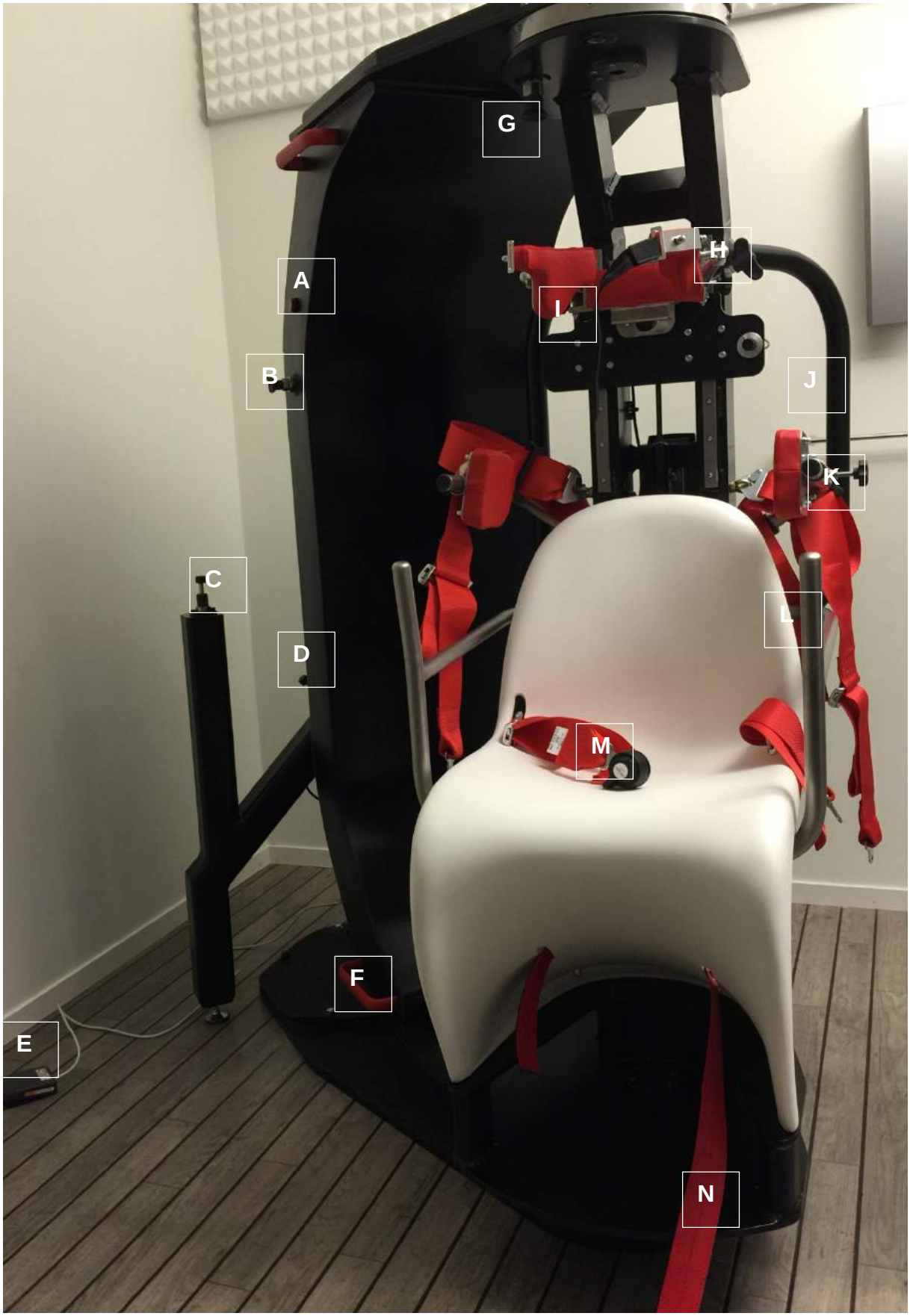
The TRV Series III.3 chair only has one lock, which covers all positions.

Remember that it is strictly forbidden to release both axles of rotation at the same time.

4.3 Charging the battery

The TRV chair is equipped with two 24V batteries – one that powers the magnetic lock for the primary frame, and one that powers the motor for the counter weight control. The two batteries are identical and may be switched around if one battery runs empty.

To charge the battery, first release it from the chair by pulling the lever on the backside of the battery's top. Next, place the battery in the wall-mounted battery charger and charge it until the yellow light in the charger station extinguishes.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Key to picture on page 19:

A Red light on when primary frame is unlocked

B Locking button for retractable limit stop

C Primary frame shock absorber for DPRM

D Primary frame shock absorber for Sémont and accentuated Epley maneuver

E Foot switch for the electromagnetic locking system (primary frame)

F Carrying handle on the primary frame

G Manual mechanical locking system to lock the secondary frame

H Headrest forward travel locking screw

I Control panel to adjust the counterweight system for the barbecue maneuvers

J Carrying handle on the secondary frame

K Lateral shim and adjusting screw

L Handle for patient

M Four-point harness

N Leg strap

5 Diagnostic maneuvers protocol proposal

IMPORTANT: Always check the supports before setting the chair in motion (see green arrows below).

5.1 General

The primary frame must not be released until the patient is in the correct position for the first diagnostic maneuver:

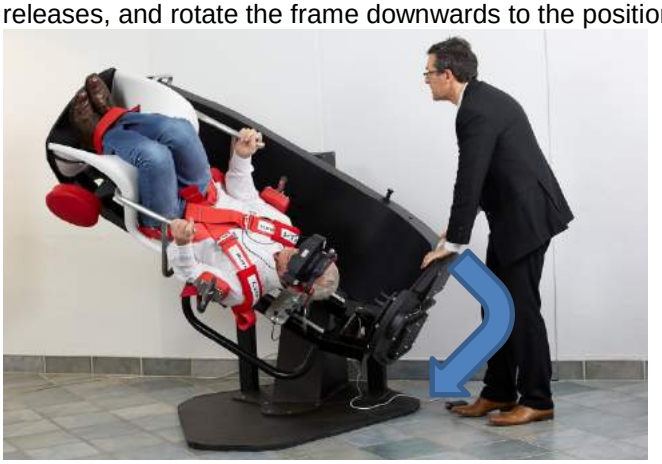
Test of Posterior and Anterior Semicircular Canals (SCCs).

Performing a Left Dix-Hallpike to test the Left Posterior and Right Anterior SCCs:

- Pull the knob on the manual lock to unlock the secondary frame

- Rotate the patient 45° over the right ear (while pulling the lock-knob) until the left handle on the secondary frame is pointing in the direction of the intended movement

- Lock the vertical arm by releasing the lock-knob. Check that the lock engages fully and in the correct notch for the Dix-Hallpike Left procedure
- Press the footswitch to unlock the primary frame . Gently push/pull the frame arm until the lock releases, and rotate the frame downwards to the position for the Left Dix-Hallpike test



- The Dix-Hallpike Left is a test of the Left Posterior SCC and of the co-planar Right Anterior SCC

Or

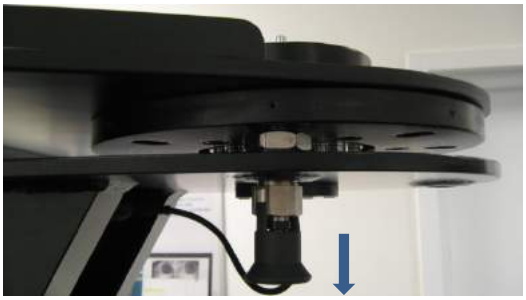
Performing a Right Dix-Hallpike to test the Right Posterior and Left Anterior SCCs:

- Pull the knob on the manual lock to unlock the secondary frame
- Rotate the patient 45° over the left ear (while pulling the lock-knob) until the left handle on the secondary frame is pointing in the direction of the intended movement

- Lock the secondary frame by releasing the lock-knob. Verify that the lock engages fully and in the correct notch for the Dix-Hallpike Left procedure.
- Press the footswitch to unlock the primary frame. Gently push/pull the frame until the lock releases, and rotate the framedownwards to the position for the Right Dix-Hallpike test of Right Posterior SCC and Left Anterior SCC.

Procedure for Examining the Lateral SCCs:

- Pull the knob on the manual lock to unlock the secondary frame



- Rotate the secondary frame until the patient's left ear is in the same plane as the intended movement of rotation

- Release the knob to lock the secondary frame
- Press the footswitch to release the primary frame magnetic lock. The red warning light for unlocked condition turns on.
- Rotate the primary frame into a horizontal position with the patient's left ear pointing to the floor
- Lock the primary frame in the horizontal position by means of the footswitch. Observe that the magnetic lock engages correctly and that the red warning light turns off.
- The lateral SCCs are now in their vertical position, and a possible left lateral canal BPPV (canalolithiasis) will be indicated by nystagmus in the geotropic form (beating towards the floor)
- To examine the right lateral canal, release the manual lock for the secondary frame and rotate the patient 180° until the right ear is pointing directly to the floor. Observe for positional nystagmus. If present, observe the nystagmus direction – geotropic or apogeotropic?

Alternative procedure to examine the lateral SCCs:

- Press the footswitch to release the magnetic lock holding the primary frame
- The patient is brought into the supine position, nose towards the ceiling

- Press the footswitch to lock the primary frame. Check that the lock engages correctly and that the red warning light switches off.
- Turn the patient 90° towards one side and 180° to the other side - then again 180° back towards the initial side, until the nature and characteristics of the horizontal positional nystagmus are sufficiently documented to determine which side needs treatment.
- The examiner may refer to Ewald's 2nd law (Paganni & Mc Clure maneuver) or to the table below to reach the correct diagnosis: If the horizontal nystagmus is beating towards the undermost ear (geotropic form), the side that needs to be treated is the side that elicits the strongest positional nystagmus when pointed towards the floor.
- If the horizontal nystagmus is beating towards the ceiling (apogeotropic form) the examiner must determine on which side the apogeotropic nystagmus is strongest – if for example this is when the left ear is down, the BPPV is in the right horizontal canal

5.2 Characteristics of positional nystagmus

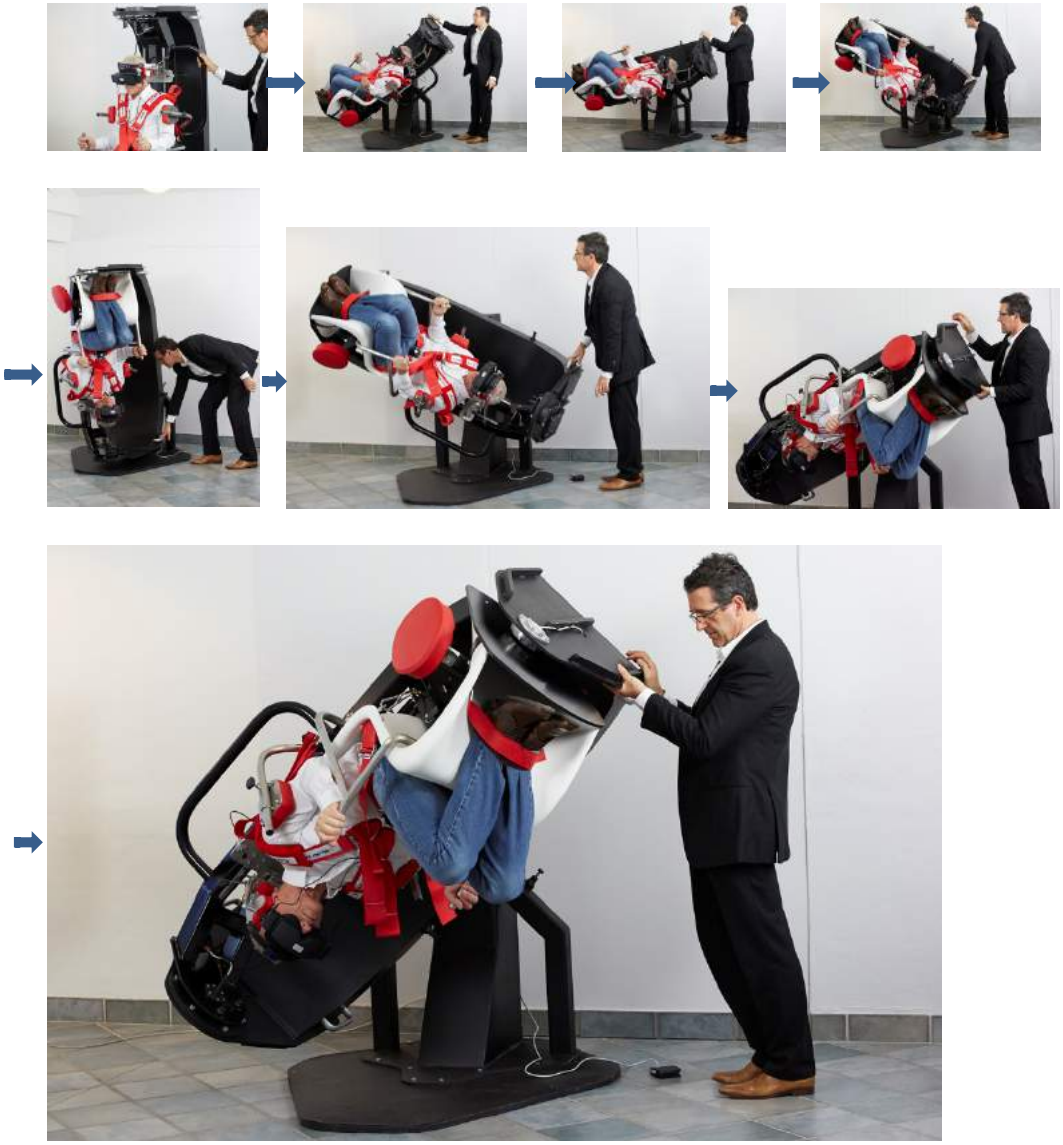
The following table may be helpful when diagnosing BPPV from eye movements during positional tests:

Head Position	Duration	Rotation / Horizontal component observed	Vertical Component	Semicircular Canal Involved and BPPV Variant
Dix-Hallpike/Sidelying Right Ear Down	<30seconds	Right Torsional	Upbeating	Right Posterior Canalithiasis
Dix-Hallpike/Sidelying Right Ear Down	>60 seconds	Right Torsional	Upbeating	Right Posterior Cupololithiasis
Dix-Hallpike/Sidelying Right Ear Down	<30 seconds	Right Torsional	Downbeating	Left Anterior Canalithiasis
Dix-Hallpike/Sidelying Right Ear Down	>60 seconds	Right Torsional	Downbeating	Left Anterior Cupololithiasis
Dix-Hallpike/Sidelying Left Ear Down	<30 seconds	Left Torsional	Upbeating	Left Posterior Canalithiasis
Dix-Hallpike/Sidelying Left Ear Down	>60 seconds	Left Torsional	Upbeating	Left Posterior Cupololithiasis
Dix-Hallpike/Sidelying Left Ear Down	<30 seconds	Left Torsional	Downbeating	Right Anterior Canalithiasis
Dix-Hallpike/Sidelying Left Ear Down	>60 seconds	Left Torsional	Downbeating	Right Anterior Cupololithiasis
Horizontal Head Roll Right/Left	<30 seconds	Geoptropic (horizontal)	n/a	Greater response when affected ear is closest to the ground → indicates HC canalithiasis
Horizontal Head Roll Right/Left	>60 seconds	Ageotropic (horizontal)	n/a	Greater response when affected ear is furthest from the ground →indicates HC cupololithiasis

Whenever a position is selected following rotation of the secondary frame it is important to check that the mechanical locking system is correctly engaged.

Before the primary frame is released, the patient should be informed what type of movement to expect as well as of the probability of an attack of vertigo during the maneuver. Throughout the various maneuvers, it is recommended that the operator keeps talking with the patient to provide reassurance.

5.3 Therapeutic maneuvers: protocol proposal for the right posterior canal



In this proposal, gravity is complemented with more or less rapid deceleration, using a limit stop against a hydraulic shock absorber (“potentiated” Sémont maneuver). It is essential to lock the system in the working position for the undermost shock absorber system.

Pull the lock button and move the retractable stop into the position where it will hit against the lower shock absorber. Release the locking button.

The limit stop is now in the working position and the Sémont maneuver can commence.

The secondary frame is rotated to an angle of 45º away from the affected side, and locked in this position.

The primary frame can then be released for smooth rotation.

Hold the primary frame by the carrying handle, standing on the side towards which the chair is to be tilted (affected side)Once the primary frame has been released, the patient will be rotated over the affected side into 45º below the horizontal plane, patient's face towards the ceiling. This often triggers a vertigo attack, accompanied by a nystagmus typical of an affection of the posterior canal (upbeating w. torsional component towards affected ear).

After a pause of about one minute, the potentiated Sémont maneuver can be performed at 270° with brisk deceleration against the purpose-designed limit stop.

With deceleration maneuvers, the rotational speed on the horizontal axis should be around 10 to 15 rpm which is approximately 2-3 seconds from start to finish at the limit stop. Excessive rotational speed is to be avoided: it does not increase therapeutic efficacy, and it only causes premature wear on the equipment as well as reduced tolerance in the patient. A liberatory nystagmus may be observed and the patient is left for about one minute in this position, then elevated to the upright position.

At this point the nystagmus may re-occur, accompanying the transition of otoconia through the crus communis, often with a predominant inferior vertical component.

The posterior canal may also be liberated by pure gravity (Epley's repositioning maneuver) from the - 45º position immobilized by the electromagnetic lock on the primary frame. The secondary frame is then rotated 180º towards the healthy side and the otoconia liberated simply by gravity and a liberatory nystagmus may occur, the patient is left for about one minute in this position, then sat up, and it is at this point again that a nystagmus may occur. 360º maneuvers is another way to free the posterior canal. The maneuver is done without the limit stop (locked in the retracted position). The Dix-Hallpike maneuver is then prolonged to make a complete revolution.

5.3.1 Therapeutic maneuvers: protocol proposal for lateral canal cupulolithiasis

The maneuver (DPRM or the so-called TRV maneuver) using hyper gravity is a 6 step maneuver with a series of 8 to 12 smooth shocks. The retractable abutment is locked in the "up" position.

The chair is tilted backwards to put the patient in the side-lying position with the involved ear towards the floor.

The first series of 8-12 shocks is performed with the abutment moving against the upper hydraulic shock absorber, allowing the particles to migrate from the cupula to the first part of the lateral canal.
After the first series of shocks the manual lock on the secondary frame can be released and the secondary frame turned 45° over the non-involved ear, and locked again by means of the manual locking system.

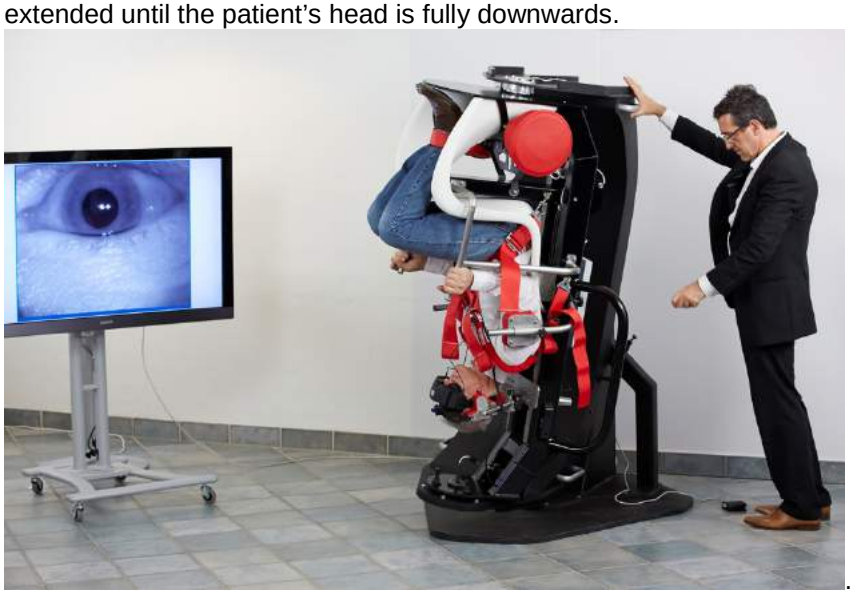
Then a new series of 8-12 shocks is performed. The patient is again turned 45° over the non-involved ear (now the nose is pointing towards the ceiling) and the same series is carried out. The 4th, 5th and 6th steps are repetitions of the previous step. The 6th step finishes with the patient in side-lying position, nose 45° downwards and the non-involved ear also downwards.

This position enables the stoma of the canal to be in its vertical orientation, allowing the particles to move into the utricle cavity. The position is maintained for 1 minute. The chair is then brought into the upright position, where the patient's support devices can then be removed.

5.3.2 Therapeutic maneuvers: protocol proposal for the anterior canal

The maneuver selected is the Lorin's method. Here, the limit stop is kept in the fully retracted position.

The patient is maneuvered in the same way as in the Dix-Hallpike maneuver, except that it is extended until the patient's head is fully downwards.



This position is held for 30 seconds, after which the patient is raised 45º in the opposite direction every 30 seconds until verticalized again. In this way, a left anterior canalolithiasis will be treated, commencing with a maneuver identical to the Dix-Hallpike maneuver for a right posterior canal and, conversely, for the right anterior canal.

6 Maintenance & care

The performance and reliability of the Vertigo Treatment and Rehabilitation (TRV) Chair will be prolonged if the following recommendations for care and maintenance are adhered to:

Regular:

- Inspect the condition of the leg strap and the headrest and change the Velcro closures at the first signs of wear
- Inspect the condition of the foam on the seating parts and their covering; repair when the foam has ceased to provide any protection

Annual:

- Inspect the magnetic lock and cylinder batteries
- Inspect all the chair nuts for tightness
- Inspect and test the four shock absorbers
- Inspect and test the electromagnetic lock
- Inspect and test the two manual locks
- Inspect and test the harness and the harness buckle
- Inspect and test the leg strap
- Inspect and test the cylinder and their fastenings
- Inspect and test the 2 axles of rotation and their bearings

Every 3 years:

- Replace the harness by releasing the four snap hooks one by one. When installing the new harness, make sure that the snap hooks are fully closed and locked:

Cleaning:

- Use a soft cloth with a non-aggressive common cleaning agent
- Do not use any solvents or aggressive cleaning liquids
- Do not use disinfectant sprays

6.1 Liability

The manufacturer shall be deemed liable for anything affecting the safety, reliability or performance of the equipment, provided it has been used in accordance with the instructions contained in this manual.

6.2 Guarantee

This equipment carries a two-year parts and labor guarantee, provided it has been used in accordance with this manual.

The guarantee excludes damage resulting from the following:

- Disassembly or modification of the equipment without the consent of the manufacturer
- The introduction of a fluid or conductive particles into the electrical components
- The use of sharp objects on the soft parts of the chair
- Loading and unloading without proper equipment

In case of a warranty issue, please contact your local Interacoustics distributor with:

- A picture of the entire chair
- a description of the defective component: how it is no longer functioning, and what the circumstances were when it ceased to function
- a picture of the defective component
- contact details for Interacoustics to reach the person or department submitting the warranty claim

Based on the information received, Interacoustics A/S will

- troubleshoot together with the person submitting the claim
- suggest an action plan for the repair
- arrange that the required spare parts are ordered and dispatched

7 Technical specifications

Dimensions:
Length: 160 cm
Width: 120 cm
Height: 190 cm
Weight: 710 kg

Working Environment:
The chair should be used in an area suitable for medical examinations.
Temperature: 10°C to 40°C
Humidity: 30% to 90%
Pressure: 700 to 1060 hPa

Disposal at End of Life:

Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

To help protect the environment, it is advisable to entrust your old chair to a collection organization able to treat equipment containing electronic components.

The magnetic lock and the counterweight system is powered by a rechargeable battery pack (Linak BAJ1 (24 V DC, 2,9 Ah)). A suitable charging station is supplied with the system.